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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Petra Cirpus

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT

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1638

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,621	Applicant(s) CIRPUS ET AL.	
	Examiner Elizabeth F. McElwain	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-23 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23 is/are allowed.
- 6) ☒ Claim(s) 1 and 4-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed February 15, 2010 has been entered.

Claims 1 and 18 are currently amended.

Claim 23 is newly submitted.

Claims 1 and 4-23 are pending and are examined on the merits.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
3. Claims 1 and 4-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knutzon et al (US 6,075,183 issued June 2000) taken with Beaudoin et al (PNAS Vol. 97, No. 12: 6421-6426) and Parker-Barnes et al (PNAS Vol. 97, No. 15: 8284-8289, July 19, 2000) and

further in view of any one or more of: GenEMBL Accession AX214446 (Heinz et al, September 6, 2001), Girke et al (Plant J 15:39-48, 1998) and Mukerji (US Patent 7,067,285).

4. The claims are drawn to a method for producing compounds in a plant that comprise any of fatty acids from 9 carbons to 24 carbons and any of one double bond to five double bonds, wherein the sum of all of said fatty acids comprises at least 1% by weight of total fatty acid content, and the plant is produced by transforming the plant with a nucleic acid encoding a delta-6 desaturase, a delta-6 elongase, and a delta-5 desaturase from *Physcomitrella patens* and/or *Phaeodactylum tricornutum*, then growing and harvesting the plant. Applicants have newly amended claim 1 to state that precursors for the production of said compounds comprised of general Formula I are present in the plant cell, plant or part thereof. However, it is understood that all plants would comprise precursors for the claimed compounds, which would include any molecules required in the pathway to produce any of fatty acids from 9 carbons to 24 carbons with any of one double bond to five double bonds, and the specification does not define the term precursor with regard to fatty acids, and therefore does not limit the interpretation of this term.

5. Knutzon et al teach producing polyunsaturated fatty acids (PUFAs) by transforming plants, including the oilseed plant *Brassica* (canola, Example 7) with constructs comprising nucleic acids encoding a delta-6 desaturase (Examples 2 and 8) or a delta-5 desaturase (Examples 1 and 7) in a construct operably linked to regulatory sequences for producing PUFAs including those with at least 20 carbon atoms and up to five carbon-carbon double bonds, and extracting the fatty acids from the plant seeds. Knutzon et al also teach that other delta-6 desaturase and a delta-5 desaturase coding sequences can be obtained from a variety of species using known methods (columns 5-6 and Example 3). In addition, Knutzon et al teach a delta-12

desaturase coding sequence (Example 4) and that two or more genes may be introduced into a host cell (column 10, lines 39-45). Knutzon et al also teach the enzymatic pathways for synthesis of PUFAs (Figures 1 and 2) using a delta-6 desaturase, a delta-6 elongase and a delta-5 desaturase, as well as other desaturases, such as a delta-12 desaturase, for example. Knutzon et al teach the desirability of producing PUFAs in plants in view of their value as dietary supplements and for pharmaceutical formulations, for example (see columns 1-2, for example).

6. Knutzon et al do not specifically teach a nucleic acid encoding a delta-6 elongase.

Knutzon et al also do not specifically teach co-transformation with the coding sequences for all three of: a delta-6 elongase, a delta-6 desaturase and a delta-5 desaturase. Knutzon et al also do not teach said coding sequences from either *Physcomitrella patens* or *Phaeodactylum tricornutum*.

7. Beaudoin et al teach a nucleic acid encoding an elongase, which is shown to act as a delta-6 elongase by production of the expected products (see page 6423, the second column), and co-expression of this elongase with a delta-6 desaturase and a delta-5 desaturase coding sequence in yeast to produce PUFAs, such as arachidonic acid (see Table 3, for example). Beaudoin et al also teach that an enzymatic pathway for production of PUFAs requires a delta-6 desaturase, a delta-6 elongase and a delta-5 desaturase (see Figure 1).

8. Parker-Barnes et al teach a nucleic acid encoding a delta-6 elongase, and co-expression of this delta-6 elongase with a delta-5 desaturase coding sequence in yeast to produce PUFAs, such as arachidonic acid. Parker-Barnes et al also teach that the enzymatic pathway for production of PUFAs that requires a delta-6 desaturase, a delta-6 elongase and a delta-5 desaturase.

9. GenEMBL Accession AX214446 is identical to SEQ ID NO: 3 encoding a delta-6 elongase from *Physcomitrella patens*.
10. Girke et al teach a delta-6 desaturase from *Physcomitrella patens* (see Figure 1, for example).
11. Mukerji teach a delta-6 desaturase from *Phaeodactylum tricornutum* (paragraph 194, Table 2, for example).
12. Given the recognition of those of ordinary skill in the art of the value of producing PUFAs in plants for the purpose of improving nutrition by transforming plants with nucleic acids encoding enzymes in the biosynthetic pathway, as taught by Knutzon et al, it would have been obvious to co-transform a plant with coding sequences for a delta-5 desaturase, a delta-6 desaturase and an elongase, given the teachings of Beaudoin et al and Parker-Barnes et al of co-transforming yeast with these three genes, and it would have been obvious to use any known coding sequences for any of these enzymes, including from species such as *Physcomitrella patens* and/or *Phaeodactylum tricornutum* that are known to comprise said coding sequences, as taught by any of GenEMBL Accession AX214446, Girke et al or Mukerji. In addition, the method used for liberating the fatty acids is a matter of choice, as is the choice of oilseed plant species, and the particular amount of a given fatty acid would be the optimization of process parameters that would depend on the gene expression, the plant species, the developmental stage of the plant or seed and the growth conditions. Thus the claimed invention would have been prima facie obvious as a whole at the time the invention was made, especially in the absence of evidence to the contrary.

13. Applicants' arguments filed February 15, 2010 have been fully considered but they are not persuasive. Applicants argue that none of the cited references teaches a delta-5 desaturase coding sequence from either *Physcomitrella patens* or *Phaeodactylum tricornutum*. The Examiner maintains that the particular species from which a nucleic acid sequence is isolated does not confer patentable distinction to said nucleic acid sequence, in the absence of evidence to the contrary. Thus, without a showing of unexpected results, it appears that the prior art sequence will have the same or similar utility as a delta-5 coding sequence from either *Physcomitrella patens* or *Phaeodactylum tricornutum*. Furthermore, Girke et al, Mukerji et al, and GenEMBL Accession AX214446 exemplify the existence of this fatty acid biosynthetic pathway in said species that produce arachidonic acid (ARA), and Knutzon et al teach that the methods for isolating delta-5 desaturase coding sequence from other organisms that produce ARA were known in the art (the paragraph bridging columns 5-6, for example, as indicated in the rejection).

14. In addition, applicants argue that the claims have been newly amended to recite that the precursors for the production of the compounds of Formula I would be present in the plant cell, plant or part thereof. The Examiner maintains that all plant cells, plants or parts of plants would comprise precursors for the fatty acids encompassed by the claims. In addition, Knutzon et al disclose fatty acid biosynthetic pathways and indicate that 18:1 and 18:2 fatty acids would be present in plants as precursors for long chain polyunsaturated fatty acids (see Figure 1, for example).

15. In response to applicants' argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the production of ARA in tobacco without the addition of exogenous substrates) are not recited in the rejected

claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

16. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant argues that in the Beaudoin and the Parker-Barnes references, the yeast required the addition of an exogenous substrate for the synthesis of the target compounds. The Examiner maintains that these references were relied on as secondary prior art references that teach that the coexpression of delta-6 elongase, delta-6 desaturase and delta-5 desaturase coding sequences was known. While yeast may have required the addition of exogenous substrates, one of ordinary skill in the art at the time the invention was made would have known that exogenous substrates would not be required to produce the compounds of Formula I in a plant cell or plant, for the reasons set forth above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Claim 23 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EFM

/Elizabeth F. McElwain/
Primary Examiner, Art Unit 1638